ISSN: 2322 - 0902 (P)
ISSN: 2322 - 0910 (O)

International Journal of Ayurveda and Pharma Research

Research Article

EFFECTIVENESS OF AN AYURVEDIC FORMULATION (ALLERGY *RAKSHAK AVALEHA*) ALONE AND IN COMBINATION (WITH ALLERGY *RAKSHAK* GHEE) FOR MANAGING ALLERGIC RHINITIS: AN OPEN-LABEL RANDOMIZED CONTROLLED STUDY

Amritpal Singh[1], Monika[1], Gurneet Singh Dhingra[2], Harveen Kaur[1], Rupinder Saini[1], Tanya Marok[3], Ankush Jagota[4]*

[1]Ayurvedic Doctor, Arogyam Ayurvedic and Panchkarma Center, Jalandhar, Punjab.
[2]MBBS, Subharti Medical College, Meerut, Uttar Pradesh.
[3]Operations Manager, Arogyam Institute, Jalandhar, Punjab.
*[4]Assistant Professor, Department of Swasthavritta, Rajiv Gandhi Government PG Ayurvedic College & Hospital, Paprola, Himachal Pradesh, India.

Article info

Article History:
Received: 23-03-2025
Accepted: 19-04-2025
Published: 15-05-2025

KEYWORDS:
Allergy Rakshak Avaleha, Allergy Rakshak Ghee, Allergic rhinitis, Ayurveda, Randomized controlled trial.

ABSTRACT

Allergic rhinitis is a common health concern worldwide, and Ayurveda offers potential alternatives to manage its symptoms and underlying causes. **Objectives:** This study evaluated the efficacy and safety of *Allergy Rakshak Avaleha* alone and in combination with *Allergy Rakshak Ghee*. **Materials and Methods**: An open-label, randomized controlled study was conducted on participants aged 18 to 65 with allergic rhinitis. Participants were randomly assigned to three groups: Group I received *Allergy Rakshak Avaleha* (½ spoon twice daily), Group II received *Allergy Rakshak Avaleha* (½ spoon twice daily) and *Allergy Rakshak Ghee* (2 drops in each nostril twice daily), and Group III received standard therapy with levocetirizine (5mg) and montelukast (10mg) once daily for 28 days. The primary outcomes were the changes in Total Nasal Symptom Score (TNSS), IgE levels, and eosinophil count at the end of the treatment (EoT), and at the 1-month follow-up. The secondary outcomes included changes in quality of life (QoL) and adverse events. **Results:** A total of 240 participants (80 per group) were enrolled in the study. All groups demonstrated a significant reduction ($p<0.05$) in TNSS, with Group II showing the greatest reduction in TNSS compared to Group III. Serum IgE levels did not show significant changes across any groups. No adverse events were reported in any of the groups. **Conclusion:** *Allergy Rakshak Avaleha,* both alone and in combination with *Allergy Rakshak Ghee,* was found to be safe and effective in managing allergic rhinitis. However, a randomized controlled trial with a larger sample size is recommended.

INTRODUCTION

Respiratory allergies, particularly allergic rhinitis, are a prevalent health concern worldwide, affecting millions of people. The condition is characterized by symptoms such as sneezing, nasal congestion, runny nose, itchy eyes, and watery eyes, which significantly impair quality of life and productivity.[1] While conventional treatments, including antihistamines, corticosteroids, decongestants, and allergen avoidance, are effective in managing symptoms, they often fail to address the root causes of allergic conditions.[2] Moreover, long-term reliance on conventional medications can lead to side effects and diminishing efficacy, prompting many to explore holistic and integrative approaches.[3] Ayurveda, an ancient system of medicine, offers promising alternatives that aim to manage not only the symptoms but also the underlying causes of respiratory allergies, thereby promoting overall health and well-being.[4,5]

Allergy Rakshak Avaleha is an Ayurvedic formulation designed specifically for managing respiratory allergies, including allergic rhinitis. The formulation is enriched with several medicinal ingredients, each of which has a significant therapeutic

Access this article online
Quick Response Code
https://doi.org/10.47070/ijapr.v13i4.3678

Published by Mahadev Publications (Regd.) publication licensed under a Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International (CC BY-NC-SA 4.0)

role. Key components include *Solanum surattense* (*Kantakari*), *Curcuma longa* (Turmeric), *Ocimum sanctum* (*Tulsi*), *Celastrus paniculatus* (*Jyotishmati*), *Phyllanthus urinaria* (*Bhumyamalaki*), *Rubia cordifolia* (Manjistha), honey, *Praval Panchamrit* (with *Mouktik*), and *Laxmivilas Ras*. Each of these ingredients is well-documented in Ayurvedic texts for their contributions to respiratory health.[6-13] *Solanum surattense*, *Curcuma longa*, and *Ocimum sanctum* are recognized for their potent anti-inflammatory and antioxidant properties, which help reduce inflammation in the respiratory tract and alleviate symptoms such as nasal congestion and irritation.[7,8] *Celastrus paniculatus* is traditionally used to enhance cognitive function and reduce stress, indirectly benefiting respiratory health by addressing stress-induced triggers of allergic reactions.[9] *Phyllanthus urinaria* is valued for its immunomodulatory properties, strengthening the body's defense mechanisms and enhancing resilience against allergens.[10] *Rubia cordifolia* offers additional anti-inflammatory benefits, particularly for both respiratory and skin health, which are often affected during allergic flare-ups.[11] Honey, a versatile natural remedy, is widely used in respiratory conditions to soothe irritation, suppress cough, and relieve discomfort caused by nasal dryness.[12] Praval *Panchamrit* (with *Mouktik*) is known for its ability to manage respiratory issues such as chest congestion and acidity, while *Laxmivilas Ras* contributes to overall vitality by supporting respiratory and digestive health.[13]

In addition to *Allergy Rakshak Avaleha*, *Allergy Rakshak Ghee*, a formulation made with pure cow ghee and Anu Taila, provides complementary benefits in the management of allergic rhinitis. Ghee, a clarified butter valued in Ayurveda, is famous for its anti-inflammatory, lubricating, and nourishing properties.[14] It contains bioactive compounds such as fatty acids, vitamins, and antioxidants, which contribute to its ability to reduce inflammation and moisturize the respiratory mucosa.[15] Its application is believed to alleviate dryness and irritation in the nasal passages, providing relief from symptoms like congestion and discomfort.[16] Anu Taila, a key component of *Allergy Rakshak Ghee*, is a medicated oil prepared using a blend of herbs, including *Sesamum indicum* (Sesame oil), *Cinnamomum camphora* (Camphor), and *Saussurea lappa* (Kustha), among others. It is traditionally used in Ayurvedic nasal therapies (Nasya) to cleanse and lubricate the nasal passages, reduce inflammation, and support upper respiratory tract health.[17] Anu Taila is particularly effective in relieving nasal congestion, reducing sinus irritation, and promoting immunity.[15] The combination of pure cow ghee and Anu Taila in *Allergy Rakshak Ghee* provides a unique approach to managing allergic rhinitis by moisturizing the nasal mucosa, improving respiratory defense mechanisms, and relieving inflammation.[6]

Despite the traditional use and preliminary evidence supporting the benefits of these Ayurvedic formulations, comprehensive clinical trials are essential to establish their efficacy and safety in managing allergic rhinitis. This study aimed to evaluate the effectiveness and safety of *Allergy Rakshak Avaleha* alone and in combination with *Allergy Rakshak Ghee* compared to standard therapy. Furthermore, it aims to offer a holistic perspective on allergic rhinitis management that has the potential to improve the health-related quality of life (HRQoL) for people suffering from allergic rhinitis.[18]

MATERIALS AND METHODS

Study design and setting

This study was an open-label, prospective, randomized controlled trial. It employed a 3-arm, parallel-group design, with participants randomly assigned to one of three groups in a 1:1:1 allocation ratio. The study was conducted at Arogyam Clinic, Jalandhar, Punjab, India, from June to October 2024.

Study population

The study included participants aged 18 to 65 years, of both sexes, diagnosed with allergic rhinitis according to the Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines. Eligibility required the presence of at least two nasal symptoms, such as sneezing, watery rhinorrhea, nasal congestion, or nasal itching, along with a Total Nasal Symptom Score (TNSS) of ≥2 on a 12-point scale at baseline. Exclusion criteria included anatomical nasal abnormalities, systemic disorders, recent treatment for malignancies, use of corticosteroids or antihistamines within a specified period prior to enrollment, and pregnancy or lactation. Written informed consent was obtained from all participants before inclusion in the study. The flow diagram of participant allocation and progression is illustrated in Figure 1.

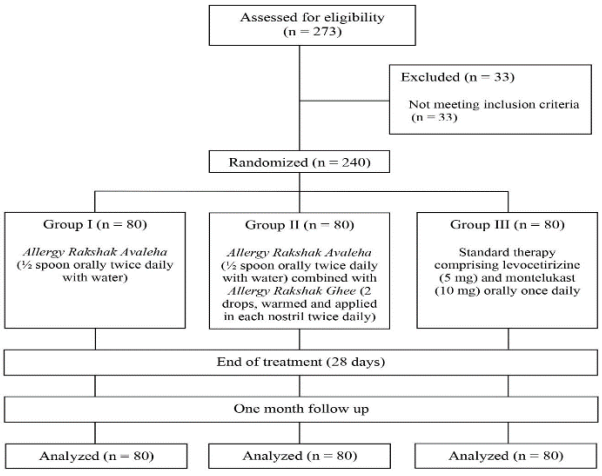
Assessed for eligibility (n = 273)
Excluded (n = 33)
Not meeting inclusion criteria (n = 33)
Randomized (n = 240)
Group I (n = 80)
Allergy Rakshak Avaleha (½ spoon orally twice daily with water)
Group II (n = 80)
Allergy Rakshak Avaleha (½ spoon orally twice daily with water) combined with Allergy Rakshak Ghee (2 drops, warmed and applied in each nostril twice daily)
Group III (n = 80)
Standard therapy comprising levocetirizine (5 mg) and montelukast (10 mg) orally once daily
End of treatment (28 days)
One month follow up
Analyzed (n = 80)
Analyzed (n = 80)
Analyzed (n = 80)

Figure 1: Consort diagram showing participant allocation and progression

Study interventions

The study included three treatment groups:

Group I: *Allergy Rakshak Avaleha* (½ spoon orally twice daily with water).

Group II: *Allergy Rakshak Avaleha* (½ spoon orally twice daily with water) combined with *Allergy Rakshak Ghee* (2 drops, warmed and applied in each nostril twice daily).

Group III: Standard therapy comprising levocetirizine (5 mg) and montelukast (10 mg) orally once daily.

The intervention period lasted 28 days. Participants received detailed instructions on how to use the medication and were asked to maintain a medication diary to monitor adherence.

Study procedure

The participants were screened based on predefined eligibility criteria, and those who did not meet the criteria were excluded from the study. A total of 240 eligible participants were enrolled and randomly assigned to one of the three groups using a computer-generated randomization sequence in Microsoft Excel.

Efficacy and safety assessment

Baseline assessments included participants' clinical and demographic characteristics, medical and allergy history, physical examination, Total Nasal Symptom Score (TNSS) assessment, health-related quality of life (HRQoL) scores, and relevant laboratory investigations. The primary outcomes were the changes in TNSS, serum IgE levels, and eosinophil count, measured at baseline, after 28 days of treatment, and at the 1-month follow-up. Secondary outcomes included changes in HRQoL scores at 28 days of treatment and at the 1-month follow-up. Safety assessments included hematological and biochemical investigations such as fasting blood sugar (FBS), full blood count (FBC), erythrocyte sedimentation rate (ESR), liver enzymes (ALT/AST), and serum creatinine levels. Adverse events were monitored throughout the study. All data were recorded in case record forms and stored in a password-protected electronic system to ensure confidentiality and security.

HRQoL assessment

The SF-36 is a self-administered questionnaire used to assess general health status. It consists of 36 questions grouped into eight domains: physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, mental health, vitality, bodily pain, and general health perception. Each domain is assigned a score ranging from 0 (representing the worst possible health) to 100 (representing the best possible health). A higher score indicates better health.

Ethics

The study was approved by the Institutional Ethics Committee of Lovely Professional University, Punjab, India (ref. no., IEC-LPU/2024/2/22). Written informed consent was obtained from all the participants. The study was registered with the Clinical Trial Registry of India (Registration ID: CTRI/2024/05/067447).

Statistical analysis

Statistical analysis was performed using SPSS version 16. The significance level was set at 0.05. Descriptive statistics were used to summarize the clinico-demographic characteristics and baseline disease attributes. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as proportions. To assess the homogeneity of participants at baseline across the different treatment groups, comparisons were made using appropriate statistical tests. For comparisons among three data subsets, either ANOVA or the Kruskal-Wallis test was used, depending on the data distribution. When comparing two data subsets, paired-sample t-tests or Wilcoxon signed-rank tests were applied, depending on the normality of the data. Post-hoc analysis was conducted for parameters that showed statistically significant differences.

RESULTS

Demographic and clinical characteristics

Out of the initial 273 participants screened for allergic rhinitis, a total of 33 participants were excluded due to not meeting the eligibility criteria. Finally, 240 participants were included in the study, with 80 participants in each of the three treatment groups: Group I (treated with *Allergy Rakshak Avaleha*), Group II (treated with *Allergy Rakshak Avaleha* combined with *Allergy Rakshak Ghee*), and Group III (treated with Levocetirizine + Montelukast). Baseline demographic and clinical characteristics were largely similar across the three groups, except for age, which showed a significant difference. The mean ages were 31.61 ± 13.21 years in Group I, 28.66 ± 11.54 years in Group II, and 24.86 ± 6.94 years in Group III. Females predominated in all groups. Clinical parameters at baseline, including Total Nasal Symptom Score (TNSS), serum IgE levels, and eosinophil counts, were comparable across the groups. The mean baseline TNSS values were 5.86 ± 2.36 in Group I, 5.16 ± 2.07 in Group II, and 5.56 ± 2.31 in Group III. The details of demographic and clinical characteristics are summarized in Table 1.

Table 1: Baseline characteristics of participants

Clinico-demographic characteristics	Group I (n = 80)	Group II (n = 80)	Group III (n = 80)	*p*-value
Age (years)	31.61 ± 13.21	28.66 ± 11.54	24.86 ± 6.94	0.001
Gender (M / F)	39 / 41	37 / 43	31 / 49	-
History of allergy	0	0	0	-
TNSS	5.86 ± 2.36	5.16 ± 2.07	5.56 ± 2.31	0.145
Serum IgE level (IU/ml)	398.28 ± 593.35	233.69 ± 321.95	435.33 ± 911.10	0.119
Eosinophil count (% of WBC)	1.88 ± 3.46	1.69 ± 2.26	1.75 ± 1.94	0.891

Efficacy assessment

Assessment of TNSS

All three groups showed a significant reduction in TNSS over time, with overall p-values of 0.001 for Group I, 0.000 for Group II, and 0.006 for Group III. Post-hoc analysis revealed that in Group I, the mean TNSS reduced from 5.86 ± 2.36 at baseline to 4.51 ± 2.33 at EoT (p = 0.001), with a slight increase to 4.89 ± 2.26 at the one-month follow-up (p = 0.025). In Group II, the mean TNSS decreased from 5.16 ± 2.07 at baseline to 3.83 ± 2.19 at EoT (p = 0.000) and further improved to 4.10 ± 1.99 at follow-up (p = 0.004). Group III showed a reduction from 5.56 ± 2.31 at baseline to 4.70 ± 2.31 after treatment (p = 0.048), with additional improvement to 4.46 ± 2.12 at follow-up (p = 0.007).

When comparing TNSS across the groups at different timelines, no significant differences were observed at baseline or the follow-up period. However, a significant difference was recorded at the end of the treatment period (p = 0.039). Post-hoc analysis identified this difference between Group II and Group III (p = 0.047), with Group II showing a greater reduction in TNSS. These findings indicate that the combination therapy used in Group II was more effective in improving TNSS. A graphical representation of TNSS improvement is shown in Figure 2. The detailed results of the TNSS assessment are summarized in Tables 2 and 3.

Assessment of serum IgE level and eosinophil count

Throughout the study period, serum IgE levels did not show any significant changes from baseline to the EoT across all groups, with values remaining within the normal range. Although a significant increase in eosinophil counts (p = 0.000) was observed after treatment in both Group I and Group II, the counts remained within the normal range. These results are shown in Table 2.

Table 2: Assessment of TNSS, serum IgE, and Eosinophil count

Assessment parameter	Group I	Group II	Group III	*p*-value
TNSS				
Baseline	5.86 ± 2.36	5.16 ± 2.07	5.56 ± 2.31	0.145
End of treatment (28 days)	4.51 ± 2.33	3.83 ± 2.19	4.70 ± 2.31	0.039
One-month follow-up	4.89 ± 2.26	4.10 ± 1.99	4.46 ± 2.12	0.066
p-value	0.001	0.000	0.006	
Serum IgE level (IU/ml)				
Baseline	398.28 ± 593.35	233.69 ± 321.95	435.33 ± 911.10	0.119
End of treatment (28 days)	369.62 ± 591.85	251.52 ± 375.23	345.21 ± 572.22	0.322
p-value	0.718	0.902	0.615	
Eosinophil count (% of WBCs)				
Baseline	1.88 ± 3.46	1.69 ± 2.26	1.75 ± 1.94	0.891
End of treatment (28 days)	2.43 ± 2.79	2.45 ± 2.26	1.84 ± 1.80	0.165
p-value	0.000	0.000	0.078	

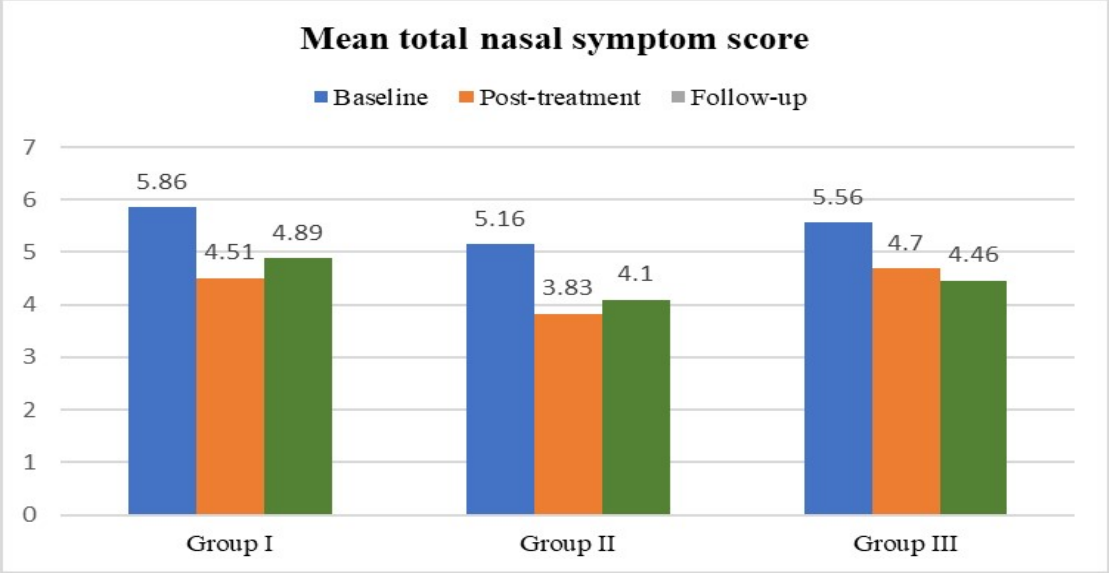

Figure 2: Graphical representation of improvement in TNSS

Table 3: Post-hoc analysis results for TNSS

Group	**Timewise comparison**	***p*-value**
Group I	Baseline vs. EoT	0.001
	Baseline vs. FU	0.025
	EoT vs. FU	0.922
Group II	Baseline vs. EoT	0.000
	Baseline vs. FU	0.004
	EoT vs. FU	1.000
Group III	Baseline vs. EoT	0.048
	Baseline vs. FU	0.007
	EoT vs. FU	1.000
Timeline	**Groupwise comparison**	***p*-value**
EoT	Group I vs. Group II	0.172
	Group I vs. Group III	1.000
	Group II vs. Group III	0.047

EoT: end of treatment; FU: follow-up

HRQoL assessment

The HRQoL assessment showed distinct patterns of improvement across the eight domains for the three study groups. At baseline, scores in all domains were comparable among the groups ($p>0.05$). Over time, Group III demonstrated significant improvement in physical functioning ($p=0.002$), while Groups I and II showed no substantial changes. In the role physical domain, significant improvement was observed in Group II ($p = 0.000$), with no notable changes in Groups I and III. All groups exhibited significant reductions in bodily pain ($p < 0.05$). In the general health domain, Groups I and II experienced substantial enhancements ($p = 0.000$), whereas Group III did not show significant improvement. Group II also showed significant progress in vitality ($p = 0.000$), while Groups I and III had no notable changes. For social functioning, significant improvements were observed in Groups I and III ($p < 0.05$), but Group II showed no significant change. None of the groups exhibited significant improvement in the role emotional domain over time. Lastly, Groups I and II demonstrated significant enhancements in mental health ($p < 0.05$), while Group III showed no substantial changes. The HRQoL assessment results for each domain are provided in Table 4.

Table 4: Results of HRQoL assessment

Domain	Timeline	Group I	Group II	Group III	*p*-value
Physical functioning	Baseline	55.31 ± 25.04	63.25 ± 21.51	58.31 ± 27.86	0.129
	End of treatment	52.44 ± 19.83	62.69 ± 18.55	60.25 ± 13.98	0.001
	Follow up	50.06 ± 20.83	63.94 ± 19.25	68.81 ± 13.65	0.000
	p-value	0.321	0.923	0.002	
Role physical	Baseline	85.31 ± 28.04	86.25 ± 23.16	91.88 ± 26.02	0.076
	End of treatment	78.94 ± 31.97	80.63 ± 32.31	85.63 ± 23.12	0.329
	Follow up	73.06 ± 38.31	96.56 ± 11.07	85.94 ± 21.36	0.000
	p-value	0.066	0.000	0.170	
Bodily pain	Baseline	52.72 ± 23.35	59.91 ± 20.67	56.97 ± 15.40	0.077
	End of treatment	69.53 ± 20.50	64.84 ± 19.68	63.19 ± 25.95	0.175
	Follow up	68.03 ± 22.69	69.38 ± 23.91	67.50 ± 25.55	0.879
	p-value	0.000	0.022	0.015	
General health	Baseline	52.44 ± 10.85	51.13 ± 6.93	51.25 ± 5.48	0.527
	End of treatment	58.75 ± 8.84	59.63 ± 5.94	48.19 ± 8.54	0.000
	Follow up	53.81 ± 11.40	64.13 ± 8.71	52.69 ± 51.69	0.038
	p-value	0.000	0.000	0.634	
Vitality	Baseline	51.75 ± 13.12	51.56 ± 9.92	50.56 ± 7.12	0.738
	End of treatment	53.56 ± 16.56	61.25 ± 11.62	54.56 ± 18.78	0.005
	Follow up	53.44 ± 16.20	64.69 ± 13.34	53.25 ± 17.41	0.000
	p-value	0.707	0.000	0.246	
Social functioning	Baseline	54.22 ± 16.15	56.56 ± 12.26	58.13 ± 11.78	0.187
	End of treatment	62.66 ± 17.95	53.91 ± 20.92	67.70 ± 17.86	0.000
	Follow up	61.09 ± 17.34	60.63 ± 17.91	66.56 ± 16.49	0.055
	p-value	0.005	0.050	0.000	
Role emotional	Baseline	84.58 ± 31.35	95.00 ± 21.93	90.83 ± 28.55	0.057
	End of treatment	82.08 ± 31.35	93.75 ± 15.09	87.50 ± 25.09	0.013
	Follow up	75.00 ± 38.43	95.00 ± 11.98	87.17 ± 24.30	0.000
	p-value	0.181	0.864	0.616	
Mental health	Baseline	55.70 ± 8.44	54.30 ± 6.06	54.65 ± 8.42	0.492
	End of treatment	61.25 ± 12.45	58.95 ± 10.68	51.30 ± 63.23	0.219
	Follow up	58.55 ± 13.86	57.10 ± 11.28	45.30 ± 12.30	0.000
	p-value	0.013	0.010	0.281	

Safety assessment

No adverse events were reported by any participants in any of the treatment groups throughout the study period. Vital parameters remained within normal limits for all participants across all groups during the entire study duration. Furthermore, hematological and biochemical parameters in all three groups were within normal limits both at baseline and at the end of the study period.

DISCUSSION

Allergic rhinitis, an IgE-mediated inflammatory condition, is characterized by symptoms like nasal congestion, sneezing, and rhinorrhea. It occurs due to an exaggerated immune response to allergens.[19] The assessment focused on symptom improvement using tools such as the TNSS, HRQoL measures, and changes in immunological markers, including serum IgE levels and eosinophil counts.

The study showed significant improvements in allergic rhinitis symptoms across all three treatment groups. Participants treated with *Allergy Rakshak Avaleha* alone (Group I) exhibited a substantial reduction in TNSS from baseline to the end of treatment, with the improvements sustained at follow-up. Similarly, those in Group II, who received the combination therapy of *Allergy Rakshak Avaleha* and *Ghee*, experienced the most distinct reduction in TNSS during the treatment period, with effects persisting at follow-up. Group III, the standard treatment group, also demonstrated significant symptom relief, consistent with the well-documented efficacy of Levocetirizine and Montelukast.[20,21] However, the magnitude of TNSS reduction was greatest in Group II, emphasizing the potential synergistic effect of the combination therapy. Post-hoc analysis further confirmed that the differences in TNSS reductions were most significant between Group II and Group III, suggesting the superior efficacy of the investigational combination therapy over the standard treatment. These findings are consistent with previous studies on alternative therapies for allergic rhinitis. For instance, one study reported a significant reduction in TNSS and IgE levels with an Ayurvedic formulation (IMMBO) compared to Levocetirizine and Montelukast.[22] Similarly, *Shatyadhi Churna*, a herbal formulation, was found to substantially improve clinical symptoms, reduce IgE levels, and enhance HRQoL in patients with allergic rhinitis.[23] Another study demonstrated the safety and efficacy of Ayurvedic formulations, including *Shirishadi Kwath* and *Anutaila*, in reducing symptoms.[4] Furthermore, the traditional Chinese medicine *Sanfeng Tongqiao Diwan* effectively alleviated symptoms, particularly in patients with severe allergic rhinitis.[24] Interestingly, the study did not observe significant changes in immunological markers such as serum IgE levels and eosinophil counts across the groups during the treatment period. This finding aligns with existing literature, which suggests that alterations in these markers often require longer durations of intervention to become apparent.[25] The observed clinical improvements, therefore, are likely mediated through mechanisms not directly reflected in these parameters within the timeframe of the study.

Levocetirizine and Montelukast are widely recognized as the standard treatments for allergic rhinitis. Levocetirizine, a selective H1 histamine receptor antagonist, works by blocking histamine, which plays an important role in early-phase allergic reactions. This mechanism provides rapid relief from acute symptoms such as sneezing, itching, and rhinorrhea. The drug's extended duration of action ensures sustained symptom control.[26] On the other hand, Montelukast, a leukotriene receptor antagonist, inhibits leukotrienes, inflammatory mediators responsible for nasal congestion, mucus secretion, and other late-phase allergic symptoms.[27] Together, these two drugs address both the early and late phases of allergic inflammation, ensuring comprehensive symptomatic relief. However, their effects remain symptomatic rather than curative, as they do not target the underlying immune dysregulation.

Allergy Rakshak Avaleha, an Ayurvedic formulation, takes a more holistic approach by addressing multiple pathways involved in allergic inflammation while improving systemic health. The formulation includes various herbal ingredients with distinct therapeutic properties. *Rubia cordifolia*, for instance, modulates immune responses and reduces hypersensitivity,[11] while *Tulsi* improves respiratory health through its antimicrobial and adaptogenic properties.[28] *Curcuma longa* acts as an anti-inflammatory and natural antihistamine, helping to alleviate nasal congestion and reduce oxidative stress.[8] *Solanum xanthocarpum* and *Phyllanthus urinaria* contribute bronchodilator and adaptogenic effects, essential for respiratory well-being.[10] Honey, another ingredient, soothes mucosal irritation and offers antimicrobial benefits.[12] Additionally, components like *Parval Panchamrit Muktayukt* and *Laxmivilas Ras* improve immune function and address systemic imbalances.[13] The inclusion of ghee in combination therapy adds value by serving as a lipophilic medium, improving the bioavailability of fat-soluble herbal actives, and reducing mucus formation.[14] The synergistic effects of these ingredients may offer not only symptomatic relief but also sustained, comprehensive benefits by targeting the underlying pathophysiology of allergic rhinitis. This mechanism may play a key role in our combination group, which demonstrated greater effectiveness compared to the other groups.

The study also explored the impact of the interventions on HRQoL, assessed using the SF-36 questionnaire. HRQoL improvements were observed across various domains for all treatment groups, reflecting the broader benefits of the therapies beyond mere symptom relief. Participants in Group I demonstrated improvements in domains such as bodily pain, general health, social functioning, and mental health. These changes suggest that *Allergy Rakshak Avaleha* not only alleviates physical symptoms but also improves social and psychological well-being, likely due to its immunomodulatory and adaptogenic properties. Group II exhibited the most comprehensive HRQoL improvements, particularly in domains like role physical, vitality, and mental health. This benefit could be attributed to the improved bioavailability of the herbal actives when combined with ghee, along

with the formulation's ability to reduce inflammation and modulate immune responses. In contrast, Group III showed significant improvements in domains related to physical functioning and bodily pain, which align with the symptomatic relief provided by Levocetirizine and Montelukast. However, the limited impact on domains such as vitality and mental health underscores the symptomatic focus of standard pharmacological treatment, as it does not address the systemic imbalances or psychosocial aspects of allergic rhinitis.

The safety profile of all three interventions was favorable, with no adverse events reported. This indicates the acceptability of *Allergy Rakshak Avaleha* and its combination with ghee as safe alternatives or adjuncts to conventional therapy. In support of this, a study reported no significant changes in laboratory parameters, including total leukocyte count (TLC), differential leukocyte count, ESR, liver function tests (LFT), and renal function tests (RFT) from baseline to the end of treatment.[24] Similarly, another study found no treatment-emergent adverse events during the study, and laboratory investigations at the end of the study showed no clinically significant changes.[22]

LIMITATIONS

While the results were promising, certain limitations must be acknowledged. The short follow-up period in this study may have limited the ability to capture long-term effects, particularly changes in immunological markers and the durability of symptom relief. Moreover, the single-center design restricts the generalizability of the findings to diverse populations. Additionally, factors such as cost-effectiveness and patient preferences between herbal and conventional treatments were not assessed, leaving scope for further exploration in future studies.

CONCLUSION

In conclusion, while standard pharmacological treatment remains effective for allergic rhinitis, the investigational products, particularly the combination of *Allergy Rakshak Avaleha* and *Ghee*, offer broader and more sustained benefits with no adverse events. Therefore, *Allergy Rakshak Avaleha* alone or in combination with Ghee can be considered as a treatment option in the management of allergic rhinitis. However, further study with a larger sample size is warranted to explore their long-term effects, optimal dosing strategies, and potential applications in other allergic and inflammatory conditions.

Source of support: Funded by Arogyam Ayurveda

Conflict of interest: Amritpal Singh, Monika, Harveen Kaur, Rupinder Saini, and Tanya Marok are associated with Arogyam Ayurveda

REFERENCES

1. Greiner AN, Hellings PW, Rotiroti G, Scadding GK. Allergic rhinitis. The Lancet. 2011; 378 (9809): 2112-22.
2. Brożek JL, Bousquet J, Baena-Cagnani CE, Bonini S, Canonica GW, Casale TB, et al. Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines: 2010 revision. Journal of Allergy and Clinical Immunology. 2010; 126(3): 466-76.
3. Abdullah B, Abdul Latiff AH, Manuel AM, Mohamed Jamli F, Dalip Singh HS, Ismail IH, et al. Pharmacological Management of Allergic Rhinitis: A Consensus Statement from the Malaysian Society of Allergy and Immunology. Journal of Asthma and Allergy. 2022; 15: 983-1003.
4. Mata S, Dave P, Bhardwaj N, Pereira C, Patel K, Bhurke LW, et al. Effect of Ayurvedic interventions in the management of Allergic Rhinitis - An open label multi-centre single arm clinical study. Journal of Research in Ayurvedic Sciences. 2023; 7(4): 206-12.
5. Padmakar S, Kumar GA, Khurana N, Kumari S, Pal B. Efficacy and safety of natural Aloe Vera gel in the treatment of stable vitiligo. Clinical Epidemiology and Global Health.2023;22: 101332.
6. Kundal P, Goswami A, Mehar K, Bisht R, Kumari S, Rajagopala M. Ayurvedic management of Allergic rhinitis with Shirisha avaleha and Anu taila pratimarsha nasya: A case report. Journal of Ayurveda Case Reports. 2023; 6(4): 211-5.
7. Tekuri SK, Pasupuleti SK, Konidala KK, Amuru SR, Bassaiahgari P, Pabbaraju N. Phytochemical and pharmacological activities of Solanum surattense Burm. f.–A review. Journal of Applied Pharmaceutical Science. 2019; 9(3): 126-36.
8. Chainani-Wu N. Safety and Anti-Inflammatory Activity of Curcumin: A Component of Turmeric (Curcuma longa). Journal of Alternative and Complementary Medicine. 2003; 9(1): 161-8.
9. Cohen MM. Tulsi - Ocimum sanctum: A herb for all reasons. Journal of Ayurveda and Integrative Medicine. 2014; 5(4): 251-9.
10. Geethangili M, Ding ST. A Review of the Phytochemistry and Pharmacology of Phyllanthus urinaria L. Frontiers in Pharmacology. 2018; 9: 1109.
11. Wen M, Chen Q, Chen W, Yang J, Zhou X, Zhang C, et al. A comprehensive review of Rubia cordifolia L. Traditional uses, phytochemistry, pharmacological activities, and clinical applications. Frontiers in Pharmacology. 2022; 13: 965390.
12. Oduwole O, Udoh EE, Oyo-Ita A, Meremikwu MM. Honey for acute cough in children. Cochrane

Database of Systematic Reviews. 2018; 4(4): CD007094.
13. Rathi B, Rajput D, Gokarn R, Mehakarkar D. Pharmaco-Therapeutic Profile of Laxmivilas Rasa-An Ayurvedic Herbo-Mineral Formulation. Journal of Indian System of Medicine. 2015; 3(3): 141-8.
14. Kataria D, Singh G. Health benefits of ghee: Review of Ayurveda and modern science perspectives. Journal of Ayurveda and Integrative Medicine. 2024; 15(1): 100819.
15. Balkrishna A, Bhatt AB, Singh P, Haldar S, Varshney A. Comparative retrospective open-label study of ayurvedic medicines and their combination with allopathic drugs on asymptomatic and mildly-symptomatic COVID-19 patients. Journal of Herbal Medicine. 2021; 29: 100472.
16. Meltzer EO. Allergic Rhinitis: Burden of Illness, Quality of Life, Comorbidities, and Control. Immunology and Allergy Clinics of North America. 2016; 36(2): 235-48.
17. Singh SK, Palawat R. A clinical study on the role of Chitrak haritaki and Anu taila nasya with a compound drug in allergic rhinitis w.s.r. to dushta pratishyay. WJPR. 2018; 7: 811-30.
18. Vijay B, Diwan B, Devkumar P, Shankar P, Vishnuprasad CN, Singh G, et al. Nasal application of sesame oil-based Anu taila as 'biological mask' for respiratory health during COVID-19. Journal of Ayurveda and Integrative Medicine. 2023; 14(5): 100773.
19. Skoner DP. Allergic rhinitis: definition, epidemiology, pathophysiology, detection, and diagnosis. Journal of Allergy and Clinical Immunology. 2001; 108(1): S2-8.
20. Shao M, Sun J, Zheng Q. Efficacy and safety of Montelukast–Levocetirizine Combination Therapy in Combined Allergic Rhinitis and Asthma Syndrome: A Systematic Review and Meta-Analysis. Journal of Asthma. 2025; 62(3): 376-85.
21. Kim MK, Lee SY, Park HS, Yoon HJ, Kim SH, Cho YJ, et al. A randomized, multicenter, double-blind, phase iii study to evaluate the efficacy on allergic rhinitis and safety of a combination therapy of montelukast and levocetirizine in patients with asthma and allergic rhinitis. Clinical Therapeutics. 2018; 40(7): 1096-107.
22. Prakash VB, Rao YK, Prakash S, Sati ST, Mohapatra A, Negi N. Proof of efficacy study to evaluate an Ayurvedic formulation in the treatment of allergic rhinitis: an open label randomized controlled clinical trial. Cureus. 2023; 15(10): e46663.
23. Dileep A, Kumar MA, Shrikrishna R. The Efficacy of Shatyadhi Churna in the Management of Vataja Pratisyaya (Allergic Rhinitis) in Children: A Randomized Controlled Clinical Trial. Journal of Ayurveda. 2024; 18(2): 109-16.
24. Hu H, Luo J, Ma J, Liang Z, Dai J, Wang W, et al. Efficacy and safety of Sanfeng Tongqiao Diwan in patients with allergic rhinitis: a single-arm clinical trial in China. Annals of Translational Medicine. 2022; 10(12): 684.
25. Kimura A, Takeda A, Ikebukuro T, Hori J. Serum IgE reduction and paradoxical eosinophilia associated with allergic conjunctivitis after dupilumab therapy. Journal of Ophthalmic Inflammation and Infection. 2021; 11(1): 3.
26. Chen C. Physicochemical, pharmacological and pharmacokinetic properties of the zwitterionic antihistamines cetirizine and levocetirizine. Current Medicinal Chemistry. 2008; 15(21): 2173-91.
27. Lagos JA, Marshall GD. Montelukast in the management of allergic rhinitis. Therapeutics and Clinical Risk Management. 2007; 3(2): 327-32.
28. Jamshidi N, Cohen MM. The Clinical Efficacy and Safety of Tulsi in Humans: A Systematic Review of the Literature. Evidence-Based Complementary and Alternative Medicine. 2017; 2017: 9217567.

Cite this article as:
Amritpal Singh, Monika, Gurneet Singh Dhingra, Harveen Kaur, Rupinder Saini, Tanya Marok, Ankush Jagota. Effectiveness of an Ayurvedic Formulation (Allergy Rakshak Avaleha) Alone and in Combination (with Allergy Rakshak Ghee) for Managing Allergic Rhinitis: An Open-label Randomized Controlled Study. International Journal of Ayurveda and Pharma Research. 2025;13(4):7-15.
https://doi.org/10.47070/ijapr.v13i4.3678

***Address for correspondence**
Dr. Ankush Jagota
Assistant Professor,
Department of Swasthavritta,
Rajiv Gandhi Government PG Ayurvedic College & Hospital,
Paprola, Himachal Pradesh, India.
Email: jagotaankush02@gmail.com

Disclaimer: IJAPR is solely owned by Mahadev Publications - dedicated to publish quality research, while every effort has been taken to verify the accuracy of the content published in our Journal. IJAPR cannot accept any responsibility or liability for the articles content which are published. The views expressed in articles by our contributing authors are not necessarily those of IJAPR editor or editorial board members.